

Section 6: 510(k) Summary

NOW 1: 7 2010

Trade Name: ChitoGauze™XR
Common Name: Wound Dressing
Classification Name: Dressing
Product Code: FRO
Predicate Device(s): Modification to ChitoGauze™ (K090026, K092357)

Company Name: HemCon Medical Technologies, Inc.
Company Address: 10575 SW Cascade Avenue, Suite 130
 Portland, OR 97223

Contact Person: Kendra Rathkey
 Regulatory Affairs Lead
Contact Phone: (503) 245.0459 x139
Contact Fax: (971) 327.5725

Date of Preparation: 01 September 2010

Description of the Device:

The ChitoGauze dressing is composed of standard polyester/rayon blend non-woven medical gauze that is coated with chitosan. This submission for ChitoGauze™XR adds a radiopaque filament to models of various dimensions of the legally marketed dressing. The ChitoGauze™XR dressings are z-folded to the appropriate size and packaged in a single heat-sealed foil pouch. The pouched dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6} . The hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding. The radiopaque filament allows for easy detection via x-ray to prevent the dressing from being inadvertently left on the wound.

Intended Use:

ChitoGauze™XR is intended to be a hemostatic wound dressing.

Indications for Use (Rx):

ChitoGauze™XR is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Technological Characteristics:

ChitoGauze™XR is technologically equivalent to the currently marketed ChitoGauze dressing. Addition of the radiopaque filament to the dressing does not affect the fundamental scientific technological characteristics of the original ChitoGauze.

Non-Clinical Performance Data:Biocompatibility

Biocompatibility has been demonstrated per ISO 10993. Addition of the radiopaque filament to the dressing has no effect upon the biocompatibility.

In Vivo Efficacy

Two separate in vivo studies were designed and conducted to establish the hemostatic efficacy of the product in different injury types created to represent the likely use of the different product sizes. In both studies the device was tested side-by-side against a competitive hemostatic dressing. The first study tested the ability of the 4 inch by 4 yard size to control bleeding in 6mm femoral perforation injury in a swine. The second study measured the ability of a two inch by two inch 8-ply size to control bleeding in a splenic capsular strip injury in a swine. In both cases, the device proved to successfully control bleeding at least as well as the competitive product used as a reference.

Reduction of Microorganisms:

ChitoGauze™ was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the level of antibacterial effectiveness; see table 2 below. The clinical utility of these results is unknown.

Table 2: Log reduction of microorganisms demonstrating level of antibacterial effectiveness of ChitoGauze™

Microorganism	Gram Stain	Log Reduction
Staphylococcus aureus (MRSA) ATCC 33591	+	>5.0
Staphylococcus aureus (MRSA) ATCC BAA-1556	+	>5.1
Staphylococcus epidermidis ATCC 12228	+	>4.4
Pseudomonas aeruginosa ATCC 9027	-	>5.1
Enterococcus faecalis (VRE) ATCC 51299	+	>5.4
Acinetobacter baumannii ATCC 15308	-	>5.2
Citrobacter freundii ATCC 8090	-	>5.2
Enterobacter cloacae ATCC 13047	-	>4.9
Streptococcus mutans ATCC 25175	+	>4.7
Streptococcus pneumoniae ATCC 10015	+	>5.4
Escherichia coli ATCC 8739	-	>4.9
Klebsiella pneumoniae ATCC 4352	-	>5.2
Streptococcus pyogenes ATCC 19615	+	5.0
Salmonella choleraesuis ATCC 10708	-	>4.6
Stenotrophomonas maltophilia ATCC 12714	-	>5.1
Citrobacter koseri ATCC 25408	-	>4.7
Proteus mirabilis ATCC 4630	-	>5.0
Proteus vulgaris ATCC 12454	-	>4.6
Moraxella catarrhalis ATCC 8193	-	>4.9
Clostridium difficile ATCC 9689	+	>5.0
Shigella species ATCC 11126	-	>4.3
Micrococcus luteus ATCC 49732	+	>5.0
Vibrio cholerae ATCC 11558	-	>4.0
Enterobacter aerogenes ATCC 13048	-	>5.0
Enterococcus faecalis (VRE) ATCC 700802	+	>5.3
Serratia marcescens ATCC 13880	-	>4.5

Sterility

A sterility validation for ChitoGauze™ XR was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Radiopacity:

The radiopacity of ChitoGauze™XR was determined via testing performed in accordance with ASTM F640-07 Method C (Standard Test methods for Determining the Radiopacity for Medical Use). The product was found to be equivalent to the radiopacity of the ASTM Radiopacity Standard (101x76x0.9 mm 99+% 1100 alloy aluminum sheet) and was therefore determined to be acceptable.

Clinical Performance Data:

No clinical data was required for evaluation of this device.

Conclusion:

The modification to ChitoGauze to add the radiopaque filament is neither a change to the intended use, nor an alteration of the fundamental scientific technology of the device.



Food and Drug Administration
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Document Control Room W-066-0609
Silver Spring, MD 20993-0002

HemCon Medical Technologies, Inc.
% Ms. Kendra Rathkey
Regulatory Affairs Lead
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Portland, Oregon 97223-4363

NOV 17 2010

Re: K102546
Trade/Device Name: HemCon Medical Technologies, Inc.
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 24, 2010
Received: November 24, 2010

Dear Ms. Rathkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

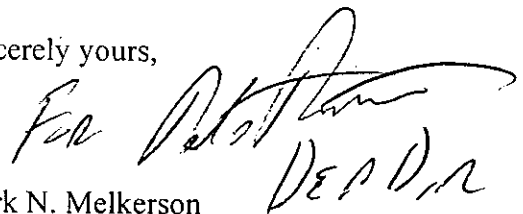
Page 2 - Ms. Kendra Rathkey

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use Statement

Applicant: HemCon Medical Technologies, Inc.
510(k) Number:
Device Name: ChitoGauze™XR

NOV 17 2010

Indications for Use (Rx):

ChitoGauze™XR is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krue for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102546